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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,323	08/16/2001	Shigeo Yoshida	11283-003002	5219

7590

04/24/2002

CHRIS T. MIZUMOTO  
Fish & Richardson P.C.  
Suite 2800  
45 Rockefeller Plaza  
New York, NY 10111

EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/931,323

Applicant(s)

YOSHIDA ET AL.

Examiner

Juliet Einsmann

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1655

### DETAILED ACTION

1. A preliminary amendment was filed canceling claims 1-3, amending claim 4, and adding claims 6-9. Claims 4-9 are pending and examined herein.

#### *Drawings*

2. The drawings submitted as Figures 4, 5, 6, and 8 are not acceptable for examination. Each of these drawings is specifically referred to in the claims, but the drawings are illegible. The claims are referring to the patterns represented in these figures, but it is impossible from the shading of the copies to ascertain the patterns contained in the figures. The new drawings should be clear depictions of the claimed patterns.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### 2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### **Timing of Corrections**

Art Unit: 1655

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

*Claim Rejections - 35 USC § 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 4-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed invention is drawn to “patterns” which are obtained by a series of steps as indicated in claim 4, of which the final recited step is requires the “detection of spots.” Thus, the claims appear to be drawn to a pattern observable by detection. Such a pattern is not statutory subject matter. A “pattern” is not a process, machine, manufacture, or composition of matter, it is more appropriately likened to a mental construct or a data set, and is descriptive material, per se, and thus not statutory subject matter because it is neither a physical “thing” nor a statutory process. Therefore, the claims patterns are not considered to be statutory subject matter.

5. Claims 5, 7, and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

Claims 5, 7, and 9 are drawn to genomic DNA analytical patterns that are “represented” by figures 4, 5, 6, or 8. The specification teaches in the examples how each of the photographed gels were obtained (Examples 1 and 2). The gels in figures 4, 5, and 6 are the result of a series

Art Unit: 1655

of steps performed on genomic Arabidopsis DNA and figure 8 is the result of a series of steps performed on genomic DNA from rice. These claims are to specific particular patterns, but the specification has not demonstrated or asserted a utility for these patterns in particular. That is, it is not clear from the specification what real world utility these particular claimed patterns have. Thus, further experimentation and analysis would be required to ascertain a substantial utility for these patterns.

Claims 5, 7, and 9 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to a genomic DNA analytic pattern obtained by the recited methodology, however, neither the claims nor the specification provide any structural information about the pattern. That is the claims do not describe what comprises the pattern.

Art Unit: 1655

Claims 5-9 are limited such that the patterns are “represented” by particular figures, but again, the claims do not contain any language or guidance as to the structure of the claimed patterns.

*Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-9 are indefinite because it is not clear exactly what comprises a “pattern.” It appears from the language of the claims that the patterns are obtained by detecting the spots of labeled, fractionated DNA, but it is not clear what structure the pattern itself has. Clarification is required.

Claims 5, 7, and 9 are indefinite over the recitation “wherein the pattern is one represented by Figs, 4, 5, 6, or 8” because the metes and bounds of this claim is unclear. The figures themselves are photographs of gels. However, as noted in the objections to the drawings above, the figures provided with the application are very difficult to interpret. Thus, it is impossible to understand the claim. Even if the figures were readable, however, the metes and bounds of the claims would still be unclear, because it is not known how the “pattern” relates to the photographs of the gel which “represent” it in the figures. It is not clear, for example, that the pattern somehow represent the intensity of the bands on the gel, if the bands on the gel must be obtained by the process outlined in the specification, etc. It is not clear if the subject matter of

Art Unit: 1655

claims 5, 7, and 9 differs from one another, as they seem to be claiming the same patterns, and if they do differ, it is not clear how they differ.

Claims 5, 7, and 9 are further rejected because they contain reference to figures. MPEP 2173.05(s) states "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). In the instant case, it would be possible to further describe the claimed patterns, at the very least, by the method steps that must be followed to obtain the claimed patterns.

Claims 6-9 are further indefinite because they depend from cancelled claims, and thus it is not clear what limitations are intended to be included in these dependent claims.

### ***Claim Rejections - 35 USC § 103***

10. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatada *et al.* (PNAS USA, 88, p. 9523-9527) in view of Deugau *et al.* (US 5508169).

Hatada *et al.* teach a genomic DNA analytical pattern which has been obtained by means of a method of analysis comprising:

- (a) treating genomic DNA with a first restriction enzyme (MluI) which is capable of cutting the genomic DNA so that the 3' end of the recognition site has a protruding sticky end
- (b) labeling the cleavage site

Art Unit: 1655

(c) treating the resulting DNA fragments with a second restriction enzyme to bring about first-dimensional fractionation

(d) treating the fractionated DNA fragments of step (c) with a third restriction enzyme to bring about second-dimensional fractionation; and

(e) detecting the spots of the labeled DNA fragments fractionated in step (d) (Hatada *et al.* describes method p. 9523, Col. 2 thru p. 9524, Col. 1).

Hatada *et al.* teach that one advantage of their method is that the scanning field of the method can be extended by the use of different kinds of landmarks (the first restriction enzyme) and further suggest the use of rare cutting enzymes (p. 9525, Col. 2). Hatada *et al.* provide examples of such enzymes, such as BssHII, an enzyme with a six nucleotide recognition site.

Hatada *et al.* provide representations of the analytical pattern in Figures 2-4.

Hatada *et al.* do not teach a genomic DNA analytical pattern made by methods in which the enzyme of step a provides restriction enzyme cleavage sites of different sequences or in which the labeling of step (b) is accomplished by ligating a labeled adapter to the restriction site.

Deagau *et al.* teach nucleic acids molecules which are indexing linkers (i.e. adapters) which can be selectively linked to unknown or non-identical cohesive ends of nucleic acid fragments released by cleavage using restriction endonucleases recognizing interrupted palindromic sequences, examples of such enzymes being *BstXI* and *BglI* (Col. 5, lines 27-32 and Col. 7, lines 45-46). Deagau *et al.* teach that "A primary instance of use of the indexing linkers is to identify specific cohesive ends of one or more DNA fragments obtained from restriction digests which yield non-identical cohesive ends. Identification may be effected by incorporation (by known methods of detectable reporter groups such as a fluorescent tag...into linker



Art Unit: 1655

molecules (Col. 9, lines 55-67).” Deagau *et al.* further teach sets of linkers with more than one type of linker, each having a ligating sequence different from the other and each being complementary to one of the different sequences of the restriction enzyme cleavage sites provided by the restriction enzyme (see for example step (ii), claim 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of Hatada *et al.* by including the use of the indexing linkers and restriction enzymes taught by Deagau *et al.* The ordinary practitioner would have been motivated to make such a modification to the methods of Hatada *et al.* by both the teachings of Hatada *et al.* (suggesting the use of alternative rare-cutting enzymes) and by the teachings of Deagau *et al.* Deagau *et al.* expressly motivates the use of their indexing linkers by suggesting that it would be a powerful extension of known methods of nucleic acid analysis “to provide a method for subsetting complex mixtures of nucleic acids in a consistent and efficient manner, to provide a level of information intermediate between the relatively crude measure of sizes of restriction fragments, and the precision of partial or complete sequence determination (Col. 3, lines 45-50),” and also that “the use of a comprehensive panel of indexing linkers provides a means for attaching specific functional modifications to selected subsets of a complex mixture of nucleic acid fragments, preferably DNA, and identifying the molecules so modified. Such a defined subset of molecules may be further resolved by additional cleavage and indexing, or by any of the established techniques such as cloning, PCR amplification, gel electrophoresis, etc. (Col. 8, lines 25-32).” Further, Deugau *et al.* specifically teach the use of the rare cutting restriction enzymes *BstXI* and *BglI* with the linkers of their invention (Col. 7, lines 45-46).

Art Unit: 1655

Thus, the genomic DNA analytical patterns of the claimed invention are prima facie obvious in light of the combined teachings of Hatada *et al.* in view of Deagau *et al.*

***Conclusion***

11. No claims are allowed.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



JEFFREY FREDMAN  
PRIMARY EXAMINER



Juliet C. Einsmann  
Examiner  
Art Unit 1655

April 18, 2002